

### **REMARKS**

This Response is filed concurrently with a Request for Continued Examination. This Communication is responsive to the Examiner's remarks presented in the Continuation Sheet to Box 5 of the Advisory Action dated November 18, 2003 and the Final Office Action mailed July 31, 2003.

In the instant Response, Applicant is making a *bone fide* attempt to advance prosecution on the merits by addressing mischaracterizations of Applicant's prior arguments of record made by the Examiner in the Advisory Action, which resulted in non-allowance of the pending claims. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections of the claims. Because Applicant is making a *bone fide* attempt to advance prosecution on the merits, the Examiner's next official communication, if not a Notice of Allowance, should not be made final.

In the Advisory Action, the Examiner indicates that Applicant's Remarks concerning the Final Office Action were considered, but did not place the application in condition for allowance. To support this position, the Examiner contends that Applicant, in its Remarks, alleged that *Bednarek's* guidewire differed from Applicant's claimed guide member only in terms of functionality. Having characterized Applicant's argument in this manner, the Examiner indicates that no patentable weight was given to such functional differences.

Applicant respectfully asserts that the Examiner has mischaracterized Applicant's argument presented in its Response to the Final Office Action with regard to differences between *Bednarek's* guidewire and Applicant's claimed guide member feature. Applicant respectfully contends that clarification of this misappreciation of Applicant's argument is both appropriate and necessary.

In its Response to the Final Office Action, Applicant distinguished the *Bednarek* apparatus from Applicant's claimed subject matter on the basis of structural differences, and not on functional differences as is erroneously

contended by the Examiner in the Advisory Action. For example, Applicant argued that:

The apparatus disclosed in *Bednarek* differs from Applicant's claimed system in several ways. Initially, *Bednarek* fails to teach a guide member which has a distal extremity or means configured for entry into a coronary sinus ostium, as is recited in Applicant's independent claims 1, 17, 18, 19, and 20.

Each of Applicant's claims 1, 17, 18, 19, and 20 recites a guide member that, among other features, includes a distal extremity or means configured for entry into a coronary sinus ostium. Clearly, recitation of a guide member having a distal extremity or means configured for entry into a coronary sinus ostium is a structural feature that must be given patentable weight.

Applicant respectfully asserts that recitation of a distal extremity or means of a guide member that is "configured for entry into a patient's coronary sinus ostium" is a structural feature, and not a functional feature as is apparently contended by the Examiner. Defining structures in terms of interrelationships or attributes they must possess has been long sanctioned in the case law. In *In re Venezia*, 530 F.2d 956, 189 U.S.P.Q. 149 (CCPA 1976), for example, the court made clear that language such as "each sleeve of said pair adapted to be fitted over the insulating jacket of one or said cables . . . imparts a structural limitation to the sleeve." *Id.* at 959 (*emphasis in original*). The court went on to clarify that language such as "adapted to be affixed" and "adapted to be positioned" defines structures or attributes of the element in question and limits the element to those configurations which allow for the stated interrelation of the element with other structures. *Id.*

Moreover, assuming *arguendo*, if Applicant's recitation of the guide member in claims 1, 17, 18, 19, and 20 was construed to include functional aspects, Applicant respectfully asserts that the Examiner's

disregarding of such functional aspects is inappropriate. For example, MPEP § 2173.05(g) makes clear that:

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what is fairly conveyed to a person of ordinary skill in the pertinent art in the context in which it is used.

Moreover, In Ex parte Bylund, 217, U.S.P.Q. 492 (Bd. Pat. App. 1981), for example, the Board made the following statement on the issue of functional language in claims:

Although we have sustained several of the Examiner's rejections, we here wish to specifically note that contrary to the Examiner's assertions, functional language in the claims must be given full weight and may not be disregarded in evaluating the patentability of the subject matter defined employing such functional language. *Id* at 498 (emphasis added).

The guidewire disclosed in *Bednarek* is used to provide a path from the left atrium transseptally back through the hemostasis valve after the transseptal technique has been performed" (column 12, lines 10-16). *Bednarek* does not describe expressly or inherently a guide member having a distal extremity configured for entry into a patient's coronary sinus ostium, as is recited in Applicant's independent claims 1, 17, 18, 19, and 20.

In addition to the mischaracterization discussed above with regard to the purported recitation of functional differences between Applicant's claimed guide member and *Bednarek's* guidewire, Applicant respectfully asserts that the Examiner has not clarified the errors in the Examiner's characterization of *Bednarek's* guidewire discussed in Applicant's Remarks in the Final Office Action Response. In its prior Response, Applicant indicated that:

In the Office Action, the Examiner contends that *Bednarek* teaches a "guide member 39 within the shaft." Respectfully, Figure 11 and supporting text indicate that element 39 is a lumen of ablation catheter 20 (see column 10, lines 25-30). Clearly, element 39 is a structure very different from the guide member or guide means recited in Applicant's claims. Moreover, the guidewire described in *Bednarek* is employed to provide a path from the left atrium transseptally to the right atrium, and is not described as useful for locating vessels, such as by incorporation of a distal extremity configured to access such vessels.

Notwithstanding this mischaracterization specifically addressed in Applicant's Remarks, the Examiner dispatched the instant Advisory Action without correcting or addressing this error, and has yet to identify how *Bednarek's* guidewire teaching discloses each and every aspect of Applicant's claimed guide member with the degree of particularity required by 35 U.S.C. § 102. Applicant respectfully requests clarification concerning *Bednarek's* guidewire teaching, so that Applicant is afforded a full and fair opportunity to evaluate the merits of the Examiner's assertions.

In the Advisory Action, the Examiner contends that *Bednarek*, as shown in Figure 11, teaches a distal tip 40 that has an opening. In its Response to the Final Office Action, Applicant argued that:

Respectfully, element 40 does not appear to be an opening, as is contended by the Examiner. Rather, element 40 is described as the distal tip of the slotted sheath 22, and the opening or slot 30 is proximal to element 40. *Bednarek* teaches, at column 9, lines 13-21, that "in a preferred embodiment, as shown in FIG. 9, the rail (16) extends through the lumen (15) of the outer guiding introducer (14), out the opening or slot (30) and then loops back through a lumen (23) within the slotted sheath (22) as is shown in FIG. 11. However, the rail need not extend through the entire length of the slotted sheath (22) and may exit through the side of the slotted sheath (22) at a location (25) proximal from the distal end (40) of the slotted sheath (22).

As is made clear at column 10, lines 60-67 of *Bednarek*, element 40 is a distal tip, not an "opening 40" as was contended by the Examiner in the Final Office Action on page 2, paragraph 1. At column 10, lines 60-67, *Bednarek* teaches that "located at the distal tip (40) of the slotted sheath (22) is the opening (44) through which the rail (16) extends through the slotted sheath (22)." Importantly, the opening 44 provides for passage of the rail 16, not the guidewire. Contrary to the Examiner's contention, *Bednarek* fails to teach a distal tip opening through which a guide member may pass in a manner contemplated in Applicant's claims 1, 17, 18, 19, and 20.

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements and their limitations must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

*Bednarek* fails to disclose, either expressly or inherently, several elements of Applicant's independent and dependent claims. *Bednarek* clearly does not teach the identical invention in as complete detail as is recited in Applicant's claims. For at least these reasons, the Examiner's rejection of claims 1-5 and 7-20 cannot reasonably be sustained.

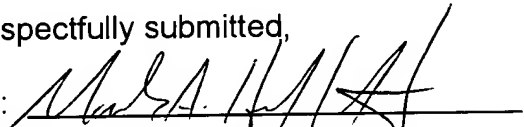
In paragraph 2 on page 3 of the Final Office Action, claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bednarek* in view of *Sugita*. The Examiner asserted that *Sugita et al.* teaches a guide wire with a plurality of indicia to measure axial movement. Applicant reasserts that the combination of *Bednarek* and *Sugita* fails to teach Applicant's invention recited in claim 6. The arguments presented above in connection with the Examiner's rejection of claim 1 under 35 U.S.C. § 102(e) as being anticipated by *Bednarek* are reasserted with respect to the Examiner's rejection of claim 6. *Sugita et al.* does not cure the

deficiencies of *Bednarek*, therefore claim 6 is patentable over the combination of *Bednarek* and *Sugita*.

It is believed that, in view of the arguments above, claims 1-20 are in condition for allowance. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding this Response, or if prosecution of this application may be assisted thereby.

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